4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-P-1188]

Determination That Cupric Sulfate Injection, Equivalent to 0.4 Milligram Copper/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Cupric Sulfate Injection, equivalent to (EQ) 0.4 milligram (mg) copper/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Cupric Sulfate Injection, EQ 0.4 mg copper/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993-0002, 240-825-9944, Kaetochi.Okemgbo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Cupric Sulfate Injection, EQ 0.4 mg copper/mL, is the subject of NDA 019350, held by Abraxis Pharmaceutical Products, and initially approved on May 5, 1987. Cupric Sulfate Injection is indicated for use as a supplement to intravenous solutions given for total parenteral nutrition, to prevent and treat copper deficiency.

In a letter dated April 17, 1995, Fujisawa USA, Inc. (the applicant at that time), notified FDA that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was being discontinued, and requested withdrawal of NDA 019350. FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the *Federal Register* of June 21, 2017 (82 FR 28322), FDA announced that it was withdrawing approval of NDA 019350, effective June 21, 2017.

Arent Fox LLP submitted a citizen petition dated November 2, 2021 (Docket No. FDA-2021-P-1188), under 21 CFR 10.30, requesting that the Agency determine whether Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Cupric Sulfate Injection, EQ 0.4 mg copper/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Cupric Sulfate Injection, EQ 0.4 mg copper/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Cupric Sulfate Injection, EQ 0.4 mg copper/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Cupric Sulfate Injection, EQ 0.4 mg copper/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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